MAY 1 6 2001 K003707 p. 1/4

510(k) Summary Date: 5/11/2001

1. Submitter Information

CardioNet, Inc.
Attn: Mr. Donald V. Canal
Vice President RAQA
6199 Cornerstone Court #106
San Diego, Ca 92121

2. Name of Device

Trade/Proprietary Name:	CardioNet Ambulatory ECG Monitor
Common/Usual Name:	Ambulatory ECG Recorder
Classification Name:	CFR §870.2920 'Telephone Electrocardiograph Transmitter and Receiver', 870.2800 'Medical Magnetic Tape Recorder'.

3. Predicate Devices

The predicate devices selected are as follows:

1. **DigiTrackPlus** Holter Recorder manufactured by Breamar, cleared by FDA under 510(k) number K993617; 870.2800 'Medical Magnetic Tape Recorder'.
2. **Reynolds LifeCard CF** recorder manufactured by Reynolds, cleared by FDA under 510(k) number K001025; 870.2800 'Medical Magnetic Tape Recorder'.
3. **Reynolds CardioCall** Looping event recorder manufactured by Reynolds, cleared by FDA under 510(k) number K972649; 870.2920 'Telephone Electrocardiograph Transmitter and Receiver'.
4. **Cordigital Examiner** Looping Event recorder manufactured by Card Guard, Inc. cleared by FDA under 510(k) number K994009. 870.2920 'Telephone Electrocardiograph Transmitter and Receiver'.

4. Device Description

The CardioNet Ambulatory ECG Monitor has the capability to perform as a Holter Monitor, or as a looping event Recorder. The device can be configured to collect 3 channels of ECG data as detailed in the user's guide. The device is comprised of two components; a patient worn Sensor unit, and a separate Monitor unit that contains the necessary electronics and firmware for ECG data storage and trans-telephonic transmission of data to an ECG analysis station.

5. Intended Use

The CardioNet Ambulatory ECG Monitor is a 3 channel ambulatory ECG monitor capable of recording and transmitting up to 24 hours of ECG data for the purpose

of cardiac monitoring and diagnosis by a medical professional. The system includes recording and trans-telephonic transmitting circuitry, a graphic LCD and firmware.

The system records ECG and transmits the ECG data to a remote central receiving station. The quality of the ECG data is suitable for analysis by another device to identify cardiac rhythm disorders, heart rate variability, reporting of QT interval, and ST changes. The device is not intended to sound any alarms.

6. Comparison to Predicate Devices

	CardioNet Ambulatory ECG Monitor (subject device)	DigiTrackPlus Holter Recorder	Reynolds LifeCard CF	Reynolds CardioCall Looping event recorder	Cordigital Examiner looping event Recorder
Maximum storage capacity.	24 hours	Up to 48 hours	26-50 hours	N/A	N/A
Event Recording time.	+/- 5 minutes from Patient Marker in event mode. Patient Marker inserted into full disclosure data in Holter mode.	Patient Marker inserted into full disclosure data	Patient Marker inserted into full disclosure data	Not Specified	6 recordings of 1-~7 minutes. The length is programmable.
Recording – Full Disclosure	Yes (Holter Mode)	Yes	Yes	No	No
Pacer Pulse Detection and reporting	Yes	Yes	Yes	Not Specified	No
A to D sampling rate (samples/sec)	250,500, 1000. Selectable	175	128	Not Specified	250
Resolution (A/D conversion bits)	12 bit	8 bit -24 hr 10 bit- 48 hr	10 bit	Not Specified	8 bit
Number of channels	2 or 3	3	2 or 3	1 or 2	1
Number of Electrodes	3	5	3, 4, or 6	2 or 3	2
Storage Type (digital or Tape)	Digital non-removable	Digital flash (removable)	Digital flash (removable)	Digital flash (non-removable)	Digital (non-removable)
Input impedance	>1 Mohm	Not specified	> 5 Mohm	Not Specified	100 Mohms
Frequency Response	0.05 Hz up to 60 Hz		0.05–40 Hz (-3 dB)	Not Specified	0.5 – 40 Hz
Communicati on Means	Cellular Phone, PSTN phone,	USB	Removable flash	Audio coupled FM tones	Audio coupled FM tones

	CardioNet Ambulatory ECG Monitor (subject device)	DigiTrackPl us Holter Recorder	Reynolds LifeCard CF	Reynolds CardioCall Looping event recorder	Cordigital Examiner looping event Recorder
	USB				
Operating temperature range	Sensor: 20°C to 45°C Monitor: 0°C to 45°C	0°C to 45°C	0°C –to 45°C	Not Specified	0 to 40°C
Storage temperature range	-20°C to 65°C	-20°C to 65°C	-20°C to 65°C	Not Specified	-20 to 65°C
Relative Humidity	5% to 95%	5% to 95%	5% to 95%	Not Specified	5% to 95%
Dimensions	Sensor –2" x 12" x 0.5" Monitor – 4.5" x 3.5" x 1.5"	3.4"x2.5"x0. 80"	96 mm x 57 mm x17.5 mm	Not Specified	55mm x 12 mm

7. Non-Clinical Performance Test Summary

The CardioNet Ambulatory ECG Monitor meets or exceeds the applicable requirements in ANSI/AAMI/ISO EC38 'Ambulatory electrocardiographs', 1998.

Several other ECG related standards have also been considered as design inputs for the CardioNet Ambulatory ECG Monitor: ANSI/AAMI EC13:'Cardiac Monitors, Heart rate meters and alarms', 1992; ANSI/AAMI EC11 "Diagnostic Electrocardiographic devices", 1991; and ANSI/AAMI EC53-1995 "ECG Cable and Lead wires".

The Sensor skin contact materials meet the requirements for surface devices, skin contact > 30 days as required in ISO10993 'FDA modified Biocompatibility' table.

The Sensor, Monitor and Base meets the applicable requirements in UL2601, and ANSI/AAMI EC1-1993, "Safe Current Limits for electromechanical Apparatus: December", 1993.

The applicable communications for the Monitor meets the applicable requirements in FCC part 15, subpart C.

8. Substantial Equivalence Conclusion

The CardioNet Ambulatory ECG Monitor is equivalent to the predicate devices as supported by the descriptive information and the performance testing to meet the

K003707 p. 4/4

applicable requirements of ANSI/AAMI EC38:1998 'Ambulatory electrocardiographs'.

9. Signature of Applicant

CardioNet, Inc.
Donald V. Canal
Vice President RAQA

Signature: _____ Date: 5/11/2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2001

Mr. David V. Canal
CardioNet, Inc.
6199 Cornerstone Court East Suite 106
San Diego, CA 92121

Re: K003707
Trade Name: CardioNet Ambulatory ECG Monitor, Model CN 1000A
Regulation Number: 870.2800
Regulatory Class: II (two)
Product Code: 74 MWJ
Dated: March 9, 2001
Received: March 13, 2001

Dear Mr. Canal:

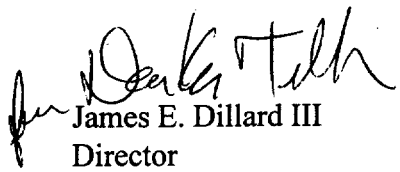
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K003707

Device Name: CardioNet Ambulatory ECG Monitor

Indications for Use:

The CardioNet Ambulatory ECG Monitor is a 3 channel ambulatory ECG monitor capable of recording and transmitting up to 24 hours of ECG data for the purpose of cardiac monitoring and diagnosis by a medical professional. The system includes recording and trans-telephonic transmitting circuitry, a graphic LCD and firmware.

The system records ECG and transmits the ECG data to a remote central receiving station. The quality of the ECG data is suitable for analysis by another device to identify cardiac rhythm disorders, heart rate variability, reporting of QT interval, and ST changes. The device is not intended to sound any alarms.

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use ✓ Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003707